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09/927,049	08/09/2001	Takeo Tanaami	010814	4111

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,049

Applicant(s)

TANAAMI, TAKEO

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 30-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30, 39 and 48 recites that the container "contains known and unknown biopolymer segments which are to be hybridized". This claim language is indefinite because it is not clear if the instant claim language is reciting biopolymer that is **immobilized** within the container for the hybridization reaction or merely biopolymer that is part of the sample to be detected in the sample fluid. The difference between the two limitations would result in devices of two different structures when applying prior art against the claims. If both segments are free in a solution and hybridize with each other, it is not clear how the segments gather at sites within the container as intended by the instant claims. Are the known segments immobilized within the container at the desired sites of gathering? Clarification and/or correction is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1744

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Choong et al.(US 6,238,909).

The reference of Choong et al. discloses a measuring device for hybridization of biopolymers. The device includes a container (10) that is separate and removable from the rest of the device. The device also includes electrodes (30) that are electrically insulated from the container. The reference also discloses that the device includes means for applying (4) an electrical signal to the electrodes to cause an unknown biopolymer segment to approach an immobilized (known) biopolymer to increase speed of hybridization and is capable of altering the direction of the electric field (See column 11, lines 54-63). In use, the device contains biopolymer segments that are both known and unknown. With respect to the claim limitations that the container is removable or movable relative to the rest of the device and/or electrodes, the reference of Choong et al. discloses that *"In some instances, it may be necessary to construct the device such that the electrodes are **moveable, and are positioned with respect to the substrate after the substrate has been appropriately positioned** (e.g., in three-dimensional structures, wherein the substrate is placed in the center of the structure, and the electrodes essentially surround the substrate in all directions). With a very large number of electrodes, e.g., ten or more, it is desirable that the configuration of the electrodes approximate that of a cylinder or sphere in either one- or three-dimensions, with the substrate being placed preferably at about the center. However, basically any arrangement of electrodes and substrate that could be*

Art Unit: 1744

employed in the invention to obtain electrostatic movement/bioconjugation of molecules are herein contemplated, and are within the knowledge and level of skill of one skilled in the art to achieve.” (See Column 9, lines 41-56).

5. Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Wen-Tung et al.(US 2001/0005718).

The reference of Wen-Tung et al. discloses a measuring device for hybridization of biopolymers. The device includes a container (5 or 1) that is separate and removable from the rest of the device. The device also includes electrodes (2 or 3) that are electrically insulated from the container. The reference also discloses that the device includes means for applying (4) an electrical signal to the electrodes to cause an unknown biopolymer segment to approach an immobilized (known) biopolymer to increase speed of hybridization and is capable of altering the direction of the electric field (See page 4, paragraph 0055). In use, the device contains biopolymer segments that are both known and unknown. With respect to the claim limitations that the container is removable or movable relative to the rest of the device and/or electrodes, the reference of Wen-Tung et al. discloses that ***“According to the invention, the substrate is detachable and separated from the electrode. The substrate can be easily replaced after the completion of the hybridization reaction. Any suitable materials can be used to prepare the substrate. Preferably, the substrate is selected from silica, glass, a semiconductor, a nylon membrane, a nitrocellulose membrane or filter paper.”*** (See paragraph [0040]).

Allowable Subject Matter

6. Claims 30-47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

The above claims would be allowable because the prior art of record fails to teach or fairly suggest a hybridization detection device that includes a container that is removable and separate from the electrodes wherein the electrodes are provided with protrusions formed at special positions corresponding to sites where the biopolymer segments gather within the container.

Response to Arguments

8. Applicant's arguments filed 27 Oct. 2003 have been fully considered but they are not persuasive.

With respect to claim 48, applicants argue that none of the prior art of record discloses or suggests a measuring device that includes a removable container so as to facilitate interchangeability of the containers (See pages 2-3 of applicants' response).

In response, as stressed in the prior art rejections above over either of the references of Choong et al. or Wen-Tung et al., both of these references disclose that the containers are independent of the electrodes and are movable with respect to the electrodes. Whether or not the

Art Unit: 1744

intention of the disclosures of the patent references was for interchangeability, the references are structurally the same as that of the structure instantly claimed.

With respect to applicants' further comments with respect to the reference of Choong et al. (See page 3 of applicants' response) that a substrate is not a container, the Examiner responds with reference to the definition of a substrate provided by the reference of Choong et al. as follows:

The "substrate" itself optionally is any solid substrate that can be employed in the invention, e.g., film, glass, Si, modified silicon, ceramic, plastic, resins, or any type of appropriate polymer such as (poly)tetrafluoroethylene, or (poly)vinylidenedifluoride. Preferred substrates according to the invention are glass and plastic. **The solid substrate can be any shape or size, and can exist as a separate entity or as an integral part of any apparatus (e.g., bead, cuvette, plate, vessel, and the like).** It further is assumed that appropriate treatment of the solid substrate (e.g., glass) will be undertaken to provide adherence of polyacrylamide (or other medium) to the glass, e.g., with gamma-methacry-oxypropyl-trimethoxysilane ("Bind Silane", Pharmacia), or other appropriate means. In particular, covalent linkage of polyacrylamide hydrogel to the solid substrate can be done as described in European Patent Application 0 226 470 (incorporated by reference). The solid substrate also optionally contains electronic circuitry used in the detection of bit molecules, or microfluidics used in the transport of macromolecules. (See column 6, lines 10-29).

Further note, the instant claims are not limited to a "hermetically sealed" container.

With respect to the reference of Wen-Tung et al., applicants argue that the instant "invention is so different from Tung that no further comment is needed".

In response, the Examiner is of the position that all of the claim limitations of claim 48 have been addressed in the prior art rejection above with respect to the Wen-Tung et al. reference. Since applicants' comments are silent as to the differences, the Examiner is of the position that instant claim 48 is anticipated for the same reasons as set forth in the 35 USC 102 rejection of the claim above.

Conclusion

Art Unit: 1744

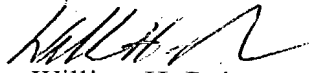
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB